IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUN PHARMACEUTICAL INDUSTRIES LTD. and RANBAXY SIGNATURE, LLC, *Plaintiffs*, v. SAPTALIS PHARMACEUTICALS, LLC, *Defendant*.	§ § § § § §	Civil Action No. 18-648-WCB

REDACTED MEMORANDUM OPINION AND ORDER

Before the Court in this Hatch-Waxman Act patent infringement action is a motion for summary judgment filed by defendant Saptalis Pharmaceuticals, LLC ("Saptalis"). Dkt. No. 69. Plaintiff Ranbaxy Signature, LLC, is the sole owner of U.S. Patent No. 6,890,957 ("the '957 patent"). Dkt. No. 1, at 3. Plaintiff Sun Pharmaceutical Industries Ltd. has exclusive marketing, promotion, distribution, and sales rights to products covered by the '957 patent on a worldwide basis. *Id.* The plaintiffs (collectively, "Sun") have asserted claims 1, 2, 7, and 9–15 of the '957 patent against Saptalis. Dkt. No. 70, at 3. Saptalis seeks summary judgment of non-infringement as to all of the claims asserted against it, arguing that the asserted claims of the '957 patent are not infringed, either literally or under the doctrine of equivalents. In this order, the Court construes the disputed terms of the asserted claims, but defers decision of the motion for summary judgment until after the close of discovery on July 19, 2019.

BACKGROUND

I. The Asserted Claims

The '957 patent is entitled "Liquid Formulation of Metformin." It issued on May 10, 2005, from an application that was a continuation of an application that issued as U.S. Patent No. 6,559,187 ("the '187 patent"). *See* Dkt. No. 70, at 2; Dkt. No. 79, at 4. The '957 patent claims priority to U.S. Provisional Application No. 60/223,391, which was filed on August 7, 2000. *See* Dkt. No. 71-12, at 2.

The '957 patent "relates to a liquid formulation of metformin and salts thereof" and to the use of that formulation "in treating hyperglycemia and/or diabetes." '957 patent, col. 1, ll. 15–17. Claim 1 is the only independent claim of the '957 patent. Dkt. No. 70, at 3–4; Dkt. No. 79, at 4.

Claim 1 states as follows:

> 1. A liquid pharmaceutical composition for oral administration which comprises a therapeutically effective amount of metformin or its pharmaceutically acceptable salt; a sweetener that does not increase the blood glucose level of a subject after ingestion thereof; a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight; a mineral acid and bicarbonate salt both present in sufficient amounts to maintain the pH of the composition in the range of about 4.0 to about 9.0; and a pharmaceutically acceptable liquid carrier.

In 2003, the U.S. Food and Drug Administration approved Sun's New Drug Application No. 021591 for the drug protected by the '957 patent. The agency then listed the patent in its publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations, also known as "the Orange Book," as covering Sun's product bearing the trade name Riomet®. Dkt. No. 1, at 3. Saptalis subsequently submitted an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Riomet®. Sun then filed this action under the

infringement provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), alleging that Saptalis's ANDA product infringes the '957 patent.

II. Sun's Infringement Contentions

In its first amended initial infringement claim charts, Sun argues that Saptalis's ANDA product meets each asserted claim limitation, either literally or under the doctrine of equivalents. The summary judgment briefing focuses on two limitations in claim 1: the sweetener limitation and the polyhydroxy alcohol limitation. Sun argues that the sweetener limitation—"a sweetener that does not increase the blood glucose level of a subject after ingestion thereof"—is met by either (or both) of two ingredients in Saptalis's ANDA product, [redacted] and an ingredient known as "[redacted] Flavor [redacted] Those ingredients allegedly provide a sweetening effect without increasing the patient's blood glucose level. Sun argues that the polyhydroxy alcohol limitation—"a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight"—is met by two ingredients in Saptalis's ANDA product, [redacted] and [redacted] which allegedly perform the same function as the polyhydroxy alcohol ingredient in the recited formulation of the '957 patent by helping to mask the unpleasant taste of the active metformin ingredient and making the formulation more viscous. Dkt. No. 71-3, at 5.

In its original infringement contentions, Sun asserted that [redacted] was the only sweetener in the accused ANDA product, and that the [redacted] and [redacted] in Saptalis's ANDA product were polyhydroxy alcohols. Dkt. No. 71-4, at 5. On January 14, 2019, Sun served an amended initial infringement claim chart on Saptalis, in which it amended its infringement contentions. Dkt. No. 80-1, at 64–70. In the amended infringement contentions, Sun alleged that both [redacted] and [redacted] Flavor [redacted] satisfied the sweetener limitation. In

addition, Sun's amended infringement contentions retreated from the position that [redacted] and [redacted] are polyhydroxy alcohols, and contended instead that they are equivalent to the polyhydroxy alcohol recited in the '957 patent. *Id.* In light of the amended infringement contentions, Sun argues that Saptalis's ANDA product infringes the '957 patent under the doctrine of equivalents.

Saptalis contends that Sun amended its original infringement contentions without any explanation. Dkt. No. 70, at 4; *see also id.* at 26–27. Sun responds that it provided Saptalis with a letter dated January 18, 2019, "which explained in detail why Sun's contentions were supplemented." Dkt. No. 79, at 8; *see* Dkt. No. 80-1, at 52–54. To the extent that Saptalis objects to Sun's amendment of its infringement contentions, the Court rejects Saptalis's argument. Sun amended its infringement contentions early in the case, giving Saptalis ample time to address Sun's new allegations in its motion for summary judgment, and there is no suggestion that Sun's amended infringement contentions were the product of bad faith on Sun's part. *See* Fed. R. Civ. P. 26(e); *see also* Dist. Of Del., *Default Standard for Discovery* § 4(c), n.3 ("As these [initial claim chart] disclosures are 'initial,' each party shall be permitted to supplement."); *AVM Techs., LLC v. Intel Corp.*, Civil Action No. 15-33, 2016 WL 7177614, at *2 (D. Del. Dec. 9, 2016).

III. Claim Construction and Summary Judgment

On October 10, 2018, the Court issued a Revised Scheduling Order assigning dates for, *inter alia*, claim construction briefing and a hearing on claim construction. *See* Dkt. No. 39. On December 28, 2018, in a letter brief to the Court, Saptalis requested that the Court modify the Revised Scheduling Order to replace the briefing and hearing on claim construction with briefing and a hearing on Saptalis's motion for summary judgment based on non-infringement. Dkt. No.

61. In its letter brief in response, Sun opposed Saptalis's request to permit early summary judgment proceedings. Dkt. No. 62. On January 4, 2019, the Court held a telephonic hearing on Saptalis's request. During the telephonic hearing, the Court granted Saptalis's request to modify the Revised Scheduling Order, permitting Saptalis to move for an early summary judgment, in conjunction with the claim construction proceedings. *See* Dkt. No. 64. The Court instructed the parties to address the remaining claim construction disputes in their summary judgment motion papers. *Id.*

ARGUMENT

I. Agreed Constructions

In their Joint Claim Construction Chart, the parties disagreed about the proper construction of the term "polyhydroxy alcohol." Sun construed "polyhydroxy alcohol" to mean "[a]ny organic polyalcohol containing more than one hydroxyl group thereon." Dkt. No. 56-1. Saptalis construed "polyhydroxy alcohol" to mean "[a]n organic polyalcohol molecule containing more than one hydroxy group." *Id.* During the January 4, 2019, hearing with the Court, however, the parties agreed that there is no material difference between the two proposed constructions of the term "polyhydroxy alcohol."

The '957 patent contains an express definition of the term "polyhydric alcohol."[1] It defines the term to mean "any organic polyalcohol containing more than one hydroxy group thereon." '957 patent, col. 4, ll. 61–63. Finding no reason to depart from the patent's definitional language,

[1] The terms polyhydroxy alcohol and polyhydric alcohol are synonymous. *See* '957, col. 9, ll. 56–58.

the Court construes the term "polyhydroxy alcohol" to mean **"any organic polyalcohol containing more than one hydroxyl group thereon."** *See id.*

II. Construction of Disputed Terms

The parties dispute the meaning of the limitation that recites "[a] liquid pharmaceutical composition for oral administration which comprises . . . a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight." Sun argues that the phrase "present in an amount of about 15 to about 55% by weight" should be given its plain and ordinary meaning, and that the term "about" means "approximately." Dkt. No. 56-1. Saptalis responds that the word "about" means "approximately," but that it "cannot include 10% or less polyhydroxy alcohol." *Id.; see* Dkt. No. 70, at 10.

During the January 4, 2019, telephonic hearing, the parties clarified the dispute over the polyhydroxy alcohol limitation, leaving three issues to be addressed in the combined claim construction and summary judgment proceedings: (1) whether the term "about 15 to about 55%" polyhydroxy alcohol includes 10% or less polyhydroxy alcohol, (2) whether the phrase "by weight" refers to the total weight of the formulation (including the weight of the liquid carrier) or only to the dry weight of the non-liquid ingredients in the formulation, and (3) whether a single ingredient can satisfy both the "sweetener" and the "polyhydroxy alcohol" limitations. *See* Dkt. No. 64. The Court will address only the first and third issues. With regard to the second issue, Sun has accepted Saptalis's construction of "by weight" for purposes of this case, i.e., Sun has agreed that the term "by weight" refers to the total weight of the formulation (including the liquid carrier). Dkt. No. 79, at 13 ("Because construing the claim term 'by weight' would not advance

this litigation, Sun will accept Saptalis's construction solely for purposes of this case."); *see* Dkt. No. 70, at 10–15.

A. Whether the term "about 15 to about 55%" includes 10% or less polyhydroxy alcohol

In its opening brief for summary judgment of non-infringement, Saptalis argues that both the intrinsic and extrinsic evidence support a conclusion that "approximately 15% polyhydroxy alcohol" cannot be construed to cover amounts of less than 10% polyhydroxy alcohol by weight. Dkt. No. 70, at 6. According to Saptalis, "the claims of the '957 patent recite various percentage weight ranges for ingredients in the claimed formulation." *Id.* In particular, Saptalis points out, the range for the sweetener in claim 3 (about 50% to about 70%) differs from the range for the sweetener in claim 4 (about 55% to about 65%) by 5% at each end of the respective ranges. *Compare* '957 patent, claim 3 *with* '957 patent, claim 4. Saptalis argues that because the patent contains separate claims for ranges that differ by only 5% at each end, "a person of ordinary skill in the art would believe that the patentee viewed a weight variation of ±5% to be significant." Dkt. No. 70, at 7.

Saptalis also points to language in the specification that it characterizes as emphasizing the significance of a weight variation of more than ±5%. The specification states that "[t]he polyhydric alcohols are present in amounts in the liquid formulation ranging from about 5 to about 55% by weight and, more preferably, from about 15 to about 40% by weight and most preferably from about 20% to about 30% by weight." '957 patent, col. 5, ll. 48-52. Saptalis argues that "[t]hese statements in the specification, like the claim language . . . , confirm that weight differences as small as 5% are meaningful." Dkt. No. 70, at 9.

Lastly, Saptalis looks to the prosecution history to support its proposed construction. Claim 1 of the '187 patent, which shares the same specification as the '957 patent, recites a polyhydroxy alcohol limitation ranging from about 5% to about 55%. '187 patent, claim 1. Saptalis contends that the weight range recited in the '187 patent shows that "the applicant knew how to claim amounts of polyhydroxy alcohol less than 15%, indeed as low as about 5%, but chose not to do so" in the patent in suit. Dkt. No. 70, at 10.

In response, Sun argues that the construction of the polyhydroxy alcohol limitation is irrelevant because "Saptalis does not literally satisfy th[at] limitation" regardless of how "about" is construed. Dkt. No. 79, at 22. Instead, Sun contends, the polyhydroxy alcohol limitation is satisfied under the doctrine of equivalents by the presence of [redacted] and [redacted] in the accused product. Nevertheless, Sun argues that, to the extent the issue is relevant, "the term 'about' should be given its ordinary and accepted meaning of 'approximately' unless the patentee clearly redefines 'about' in the specification, which was not done here." *Id.* at 12. Sun states that "[t]he portions of the patent cited by Saptalis to support [its] construction never say that 'about' denotes a strict numerical or percent variation in any context." *Id.* at 23. Therefore, according to Sun, "Saptalis's attempt to impose a strict 10% lower bound on the meaning of the term 'about 15%' is inconsistent with Federal Circuit precedent, which holds that the plain and ordinary meaning of the term 'about' is 'approximately' unless otherwise specified." *Id.* at 22 (citing *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369–70 (Fed. Cir. 2005)); *see also Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1389 (Fed. Cir. 2014); *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455, 2016 WL 7210837, at *12 (E.D. Tex. Dec. 13, 2016); *Cipher Pharm. Inc. v. Actavis Labs. FL, Inc.*, 99 F. Supp. 3d 508, 518 (D.N.J. 2015).

The Court agrees with Sun that the term "about" should be given its ordinary and accepted meaning of "approximately." The Federal Circuit has explained that "when a patent 'repeatedly and consistently' characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization." *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370 (Fed. Cir. 2016). The term "about" is repeatedly and consistently used throughout the written description and the claims without reference to a particular weight range or other parameters. *See, e.g.*, '957, col. 3, ll. 12–15 ("about 40% to about 80% by weight of a sweetener, about 5% to about 55% by weight polyhydroxy alcohol and about 0.01% to about 5% by weight alkyl hydroxyethylcellulose"); col. 3, ll. 21–22 ("the pH of the formulation ranges from about 4 to about 9"); col. 4, ll. 8–11 ("Preferably, a therapeutic [sic] effective amount of metformin or salt thereof ranges from about 10 mg/kg/day to about 40/mg/kg/day and more preferably from about 14 mg/kg/day to about 38 mg/kg/day."); claim 6 ("alkyl hydroxyethylcellulose . . . ranging from 0.08% to about 0.2% by weight"); claim 14 ("pH ranges from about 4.2 to about 7.0").

Saptalis focuses on the differences of 5% in the minimum and maximum sweetener weights between claim 3 ("amounts ranging from about 50% to about 70%") and claim 4 ("amounts ranging from about 55% to about 65%") and argues that those differences indicate that the patentee regarded a difference of 5% by weight as the limit of the term "about." The patent, however, does not consistently draw such a distinction at the 5% level. Claim 7, for example, recites the composition of claim 1, with the exception that the polyhydroxy alcohol component "is present in amounts ranging from about 15% to about 40% by weight." The difference between the 15-55% range set forth in claim 1 and the 15-40% range set forth in claim 7 could be taken, consistent with Saptalis's reasoning, to suggest that a 15 percent difference (the difference between the 55%

maximum in claim 1 and the 40% maximum in claim 7) is a material difference and thus is indicative of the limits of the term "about."

Similarly, as noted, the written description of the '957 patent describes the "most preferred" formulation as containing "about 5% to about 55% by weight polyhydroxy alcohol." *Id.*, col. 3, ll. 9–14. That language suggests that the formulation of claim 1, although recited as requiring a minimum concentration of "about 15%" of polyhydroxy alcohol, would be equally effective with a minimum concentration of "about 5%" of polyhydroxy alcohol. From that, it is fair to conclude that the term "about 15%" is not limited to amounts greater than 10%.

Elsewhere in the written description, the patent distinguishes among concentration ranges of polyhydric alcohols of (1) "about 5 to about 55% by weight" in the liquid formulation, (2) "more preferably, from about 15 to about 40% by weight," and (3) most preferably from about 20% to about 30% by weight." *Id.*, col. 5, ll. 48–52. Those examples suggest that the differences in the polyhydroxy alcohol levels necessary to make a material difference in the formulation vary between 5% and 15%. Saptalis's argument based on the difference in sweetener concentrations in claims 3 and 4 is therefore unconvincing in light of the wide and varying ranges referred to elsewhere in the patent as necessary to make a material difference in the formulation.

Construing "about" to mean "approximately" also aligns with the Federal Circuit's instructions that "[g]enerally claim terms should be construed consistently with their ordinary and customary meanings," and that "the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck & Co.*, 395 F.3d at 1370. Here, notwithstanding the specification's discussion of polyhydroxy alcohol weight preferences that vary by ±5%, *see* '957 patent, col. 5, ll. 48–52, the term "'[a]bout' is not

defined either explicitly or by implication by the specification." *Ferring B.V.*, 764 F.3d at 1389. For that reason, as the Federal Circuit stated in the *Ferring* case, "We think that the district court did not err in giving the term 'about' its ordinary meaning and in refusing to give it a more specific construction." *Id.*

Accordingly, the Court construes the term "about 15 to about 55%" to mean **"approximately 15 to approximately 55%."**

B. Whether a single ingredient can satisfy the "sweetener" and "polyhydroxy alcohol" limitations

The next issue is whether a single ingredient, a polyhydroxy alcohol that has a sweetening effect on the formulation, can satisfy both the "sweetener" and "polyhydroxy alcohol" limitations of claim 1 of the '957 patent. At the outset, Sun questions whether this issue should be treated as a matter of claim construction rather than as a question of infringement. Dkt. No. 79, at 13. Saptalis contends that it is a claim construction issue. Citing *Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, 787 F.3d 1359 (Fed. Cir. 2015), and *Supernus Pharmaceuticals, Inc. v. TWI Pharmaceuticals, Inc.*, 265 F. Supp. 3d 490 (D.N.J. 2017), Saptalis points out that the Federal Circuit and district courts have addressed such questions as matters of claim construction.[2] *See* Dkt. No. 87, at 3. The Court agrees with Saptalis and will treat this issue as a claim construction issue. *See Shire Dev., LLC*, 787 F.3d at 1366–68 (holding, as a matter of claim construction, that "[t]he separation of these elements within the claims indicates that the claim requires two separate matrices"); *see also Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011)

[2] Saptalis also correctly notes that the Court asked for this issue to be addressed at claim construction. Dkt. No. 87, at 3.

(explaining that in *Becton, Dickinson & Co. v. Tyco Healthcare Group*, 616 F.3d 1249 (Fed. Cir. 2010), "the terms 'hinged arm' and 'spring means' were construed to require separate structures—a requirement which carried through to the infringement analysis").

In any event, Sun argues this issue does not matter. According to Sun, the Court does not need to address whether it is legally permissible to double-count [redacted] first as the sweetener, and then in combination with [redacted] as an equivalent to polyhydroxy alcohol—because expert testimony supports Sun's infringement contention that the [redacted] flavor in Saptalis's ANDA product also satisfies the sweetener limitation. *See* Dkt. No. 79, at 38. The Court will address that argument in its decision on Saptalis's motion for summary judgment.

On the merits, Saptalis argues that "[w]hile the specification of the '957 patent explains that a single ingredient can act as different claimed excipients in different formulations, a single ingredient cannot act as more than one claimed excipient in the claimed formulation." Dkt. No. 70, at 15. For support, Saptalis states that (1) the sweetener and the polyhydroxy alcohol are separately recited in the asserted claims, (2) some dependent claims adjust the properties of either the sweetener or the polyhydroxy alcohol, but not both, (3) it would be difficult for a single ingredient to fall within the concentration ranges for both the sweetener and the polyhydroxy alcohol limitations in claim 4,[3] and (4) the specification consistently describes the sweetener and the polyhydroxy alcohol as separate ingredients. *Id.* at 15–18.

[3] Claim 4 requires a sweetener "in amounts ranging from about 55% to about 65%," and incorporates the requirement of independent claim 1 that the polyhydroxy alcohol be present "in an amount of about 15 to about 55%." Those two amounts overlap only at the "about 55%" point, so the only way a single ingredient could satisfy both requirements would be for the amount of the ingredient to be "about 55%."

Sun counters that a person of skill in the art would understand that the sweetener limitation and the polyhydroxy alcohol limitation "share overlapping functionality." Dkt. No. 79, at 41. According to Sun, one of the functions of the polyhydroxy alcohol "is to mask the bitter taste of metformin and its salts," and the function of the sweetener "is to impart a sweet taste while not increasing the blood glucose levels of the patient." *Id.* at 41–42. Therefore, Sun argues, "the same ingredient could function both to impart a sweet taste . . . and mask the bitter taste of metformin and its salts." *Id.* at 42.

The Court finds that the '957 patent does not contemplate that a single ingredient can satisfy both the "sweetener" and the "polyhydroxy alcohol" limitations. In the claims, the polyhydroxy alcohol and sweetener are consistently referred to as distinct ingredients. *See* '957 patent, claim 1 ("a sweetener that does not increase the blood glucose level of a subject after ingestion thereof; a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight"); claim 3 ("the sweetener is present in amounts ranging from about 50% to about 70% by weight"); claim 7 ("the polyhydroxy alcohol is present in amounts ranging from about 15% to about 40% by weight").

The specification also refers to the sweetener and the polyhydroxy alcohol as separate components of the metformin liquid formulation, in which both components are separately listed in the specified embodiments of the invention. As noted by Saptalis, "every exemplary formulation in the specification with the same ingredients recited in the claims of the '957 patent includes at least one sweetener and at least one separate polyhydroxy alcohol." *See* Dkt. No. 70, at 17; '957 patent, col. 13, line 52, through col. 14, line 35; *see also id.* at col. 3, ll. 2–5 ("In one preferred embodiment, the liquid carrier contains at least one of the following components: a

polyhydroxy alcohol, a sweetener . . . ."); col. 4, ll. 54–58 ("[T]he present liquid formulation comprises . . . the liquid carrier and at least one or two of the following: a sweetener, a polyhydroxy alcohol, an alkyl hydroxy ethyl cellulose, or combination thereof.").

As a further indication that the sweetener and polyhydroxy alcohol limitations cannot be satisfied by a single ingredient, the specification discusses the preferred ratios between the polyhydroxy alcohol and the sweetener. *Id.* at col. 5, ll. 60–63 ("It is preferred that the weight ratio of polyhydric alcohol to sweetener, if present, ranges from about 1:1 to about 6:1 and . . . most preferably, from about 2:1 to about 3:1."). A reference to the ratios of those components would have no meaning if a single component could satisfy both limitations. Thus, while it may be true that certain components, such as sugar alcohols, could act as sweeteners in the formulation and could also satisfy the polyhydroxy alcohol limitation, the structure of the claims and the text of the specification make clear that the '957 patent requires separate ingredients to satisfy the sweetener and polyhydroxy alcohol limitations for purposes of literal infringement.

The cases cited by Sun merely stand for the uncontroversial point that ordinarily a single component of an accused product can satisfy more than one claim element. In *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d at 1231, the Federal Circuit addressed the question whether the terms "cutting box" and "dust collection structure" are district terms that can be infringed only by a device that has separate structures corresponding to the distinct claim elements. The court concluded that "the specification teaches that the cutting box may also function as a 'dust collection structure' to collect sawdust and wood chips generated during the wood cutting process." *Id.* at 1231–32. Given the teachings in the specification, the court held that the claim terms did not require separate structures. *Id*. at 1232.

This Court's findings in the present case are not to the contrary, as the Court has relied on guidance from the claims and the written description to determine whether a single ingredient can satisfy both limitations. The Court has concluded that in this case, unlike in *Powell*, the claims and specification clearly teach that the polyhydroxy alcohol and the sweetener must be separate components.

The Federal Circuit's decision in *Intendis GmbH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355 (Fed. Cir. 2016), on which Sun heavily relies, also fails to support Sun's claim construction analysis. In *Intendis*, the Federal Circuit affirmed a district court's findings, for purposes of the doctrine of equivalents, that the isopropyl myristate in the accused generic product served the same purpose as the triglyceride and lecithin recited in the asserted claim and therefore supported the judgment of infringement. 822 F.3d at 1361–63. Importantly, the Federal Circuit's focus on the functionality of two of the claim limitations was directed to determining infringement under the doctrine of equivalents, and not claim construction. It is therefore inapplicable to the claim construction issue presented here.

The Court recognizes that the relevant claim elements in the '957 patent "share overlapping functionality," Dkt. No. 79, at 41, such that a single ingredient could be both a sweetener and a polyhydroxy alcohol. However, the Court must look beyond the functionality of the claim terms to determine whether the patentee intended a single ingredient to satisfy both the sweetener and the polyhydroxy alcohol limitations. *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) ("The prosecution history, specification, comparison with other claims in the patent, and other evidence may require that two terms in a claim refer to different structures" (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en

banc))); *see also Supernus Pharm.*, 265 F. Supp. 3d at 499 ("The Court agreed that [a construction that permitted a single excipient that serves several different functions to satisfy multiple claim elements] was not envisioned by the inventors or in the specifications or claim language of the Patents-in-Suit."). Having done so, the Court rejects Sun's argument that claim 1 of the '957 patent contemplates that the sweetener and polyhydroxy alcohol limitations can be satisfied by a single component.

III. Saptalis's Motion for Summary Judgment of Non-Infringement

In its motion for summary judgment of non-infringement, Saptalis argues that its ANDA product does not infringe two of the limitations of claim 1 of the '957 patent: (1) the sweetener limitation ("a sweetener that does not increase the blood glucose level of a subject after ingestion thereof"), and (2) the polyhydroxy alcohol limitation ("a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight"). *See* Dkt. No. 70, at 18–19; Dkt. No. 79, at 1–2. According to Saptalis, summary judgment in its favor should be granted based on each of those two limitations.

As has become clear during the pre-trial proceedings, a key portion of Sun's case against Saptalis turns on whether Sun is entitled to the benefit of the doctrine of equivalents and can prove infringement of the '957 patent by equivalence. In the course of the briefing of Saptalis's early summary judgment motion, and at the hearing on Saptalis's motion, Sun urged the Court not to decide the motion until after the close of discovery, so as to ensure that Sun would have the benefit of discovery in responding to the arguments made by Saptalis.

The Court notes that fact discovery in this case will close on July 19, 2019. Because that date is approaching and little would be gained by issuing a decision on summary judgment at this

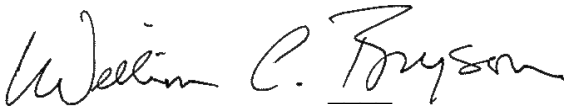
point, the Court has decided to defer resolving the summary judgment motion until after that time. Postponing resolution of the summary judgment motion until after the completion of fact discovery will not be unduly burdensome on the parties. In addition, it will enable Sun to make use of anything produced during fact discovery and will avoid the possibility that, in the event the Court were to deny the motion, Saptalis would seek to file a renewed motion based on information developed in the course of the fact discovery proceedings.

In urging the Court to postpone decision of the summary judgment motion until the completion of discovery, Sun advocated waiting until the completion not only of fact discovery, but of expert discovery as well. The Court is not persuaded that it is necessary to await the completion of expert discovery. Sun has already submitted a declaration of its expert, Mansoor A. Kahn, and Saptalis has submitted a declaration from its expert, Frank A. Chrzanowski. If either party has relevant expert evidence that was unavailable for submission at the time the initial summary judgment briefs were filed, the Court will accept such evidence as part of the parties' supplemental submissions on July 29, 2019. Resolving the summary judgment motion after the completion of fact discovery but before the completion of expert discovery will therefore not deprive either party of the opportunity to point to evidence relevant to the decision of the summary judgment motion. Depending on how the summary judgment motion is decided, a ruling on the motion prior to the completion of expert discovery could save the parties the considerable expense entailed in expert discovery or, at minimum, could provide significant additional information to the parties regarding the Court's assessment of the issues that will be contested at the bench trial currently scheduled for February 18, 2020.

Accordingly, the Court will defer ruling on Saptalis's summary judgment motion until after fact discovery closes on July 19, 2019. The Court will give the parties 10 days to file supplemental briefs no more than 2500 words in length (not counting attachments) addressing the factual and legal aspects of any matter that may have been the subject of discovery or additional expert evidence. The Court will rule on the summary judgment motion after receiving those briefs on July 29, 2019.

IT IS SO ORDERED.

SIGNED this 10th day of June, 2019.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE